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No. 07-521

IN THE

Supreme Court of the United States

RICHARD WARD, ET AL.,

PETITIONERS

v.

WASHINGTON UNIVERSITY,

RESPONDENT.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Eighth Circuit

REPLY IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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I
INTRODUCTION

The Research Participants' petition for certiorari explained that the Eighth Circuit improperly ignored the Common Rule – federal regulations intended to protect patients' rights in dealing with federally funded research institutions – in holding that Washington University (the "University") had become the owner of Petitioners' tissue samples. The University now claims that review is unwarranted because the Court of Appeals declined to address the meaning of the pertinent federal regulation. Br. in Opp. at 14-15. Yet the Eighth Circuit's failure even to acknowledge a dispositive federal issue is a reason that certiorari *should* be granted. This Court should make clear that a lower court cannot shield a litigated federal issue from review just by declining to consider it. The Court of Appeals' reversible error was not just in misapplying a dispositive federal regulation but in ignoring its existence and, in the process, the role of the federal government in protecting individual rights and the integrity of medical research.

Indeed, the University's brief in opposition now confirms that Petitioners' interpretation of the regulation is correct. The Common Rule prohibits federally funded research institutions from seeking consent from participants using "exculpatory language through which the subject ... is made to waive or appear to waive any of the subject's legal rights." 46 C.F.R. § 46.116. The University's Brief includes a November 2007 letter to the University from the Office of Human Research Protection ("OHRP"), the agency in charge of enforcing the

Common Rule, which states that OHRP finds language that "waives *any* such legal rights on the part of research subjects to be exculpatory." Br. in Opp. 5a (emphasis added). Had the Eighth Circuit adopted this correct interpretation, it could not have ruled that Petitioners had waived their ownership rights in their tissue and blood – a ruling that eviscerates the federal rights guaranteed to research participants and renders meaningless the Common Rule's prohibition of exculpatory language.

Faced with an agency interpretation supporting Petitioners, the University makes several specious arguments against granting certiorari. Contrary to the University's arguments, the petition does present a federal question that was fully litigated below. Moreover, the resolution of that federal question not only would be outcome-determinative here, but also would have a significant impact on the way that research is conducted around the country.

For these reasons, which are discussed in detail below, Petitioners ask that the Court grant the petition, or, in the alternative, seek the views of the Solicitor General concerning the meaning of the Common Rule and the advisability of granting review in this case.

ARGUMENT IN REPLY

1. The University's brief in opposition begins with a series of fallacious arguments advanced in an effort to show that the federal question presented by Petitioners is not properly before the Court. Those arguments are easily rebutted. The University's primary argument is that review is unwarranted

because the Eighth Circuit (although not the District Court) failed to consider the meaning of the federal regulation. But an appellate court may not shield a dispositive litigated federal issue from review simply by ignoring it – especially where, as here, its decision is likely to be viewed by other courts as having resolved that issue.

In an attempt to excuse the Eighth Circuit's failure to discuss the effect of the Common Rule, the University claims that Petitioners did not raise the federal preemption defense to the University's state-law claim of ownership of the tissue samples. Br. in Opp. at 13-17. That is flatly untrue. Although Petitioners also argued that they should prevail as a matter of state law, they quite expressly argued that the Common Rule barred a contrary interpretation of state law as permitting the transfer of title to the samples. Petitioners made this argument both in the trial court – which did address, albeit incorrectly, the meaning of the regulation – and in the appellate court. RP Br. at 11 (E.D. Mo. filed June 15, 2005); RP Br. at 29-33 (8th Cir. filed July 12, 2006); RP Reply Br. at 20 (8th Cir. filed Sept. 21, 2006) ("[T]he Common Rule's prohibition on exculpatory language, 45 C.F.R. § 46.116, bars waiver of the RPs' ownership rights in the samples provided for research."); *see also* RP Pet. at 9. Indeed, while the University now asserts the preemption issue was not presented, it devoted several pages of its own responsive appellate brief to the effect of the Common Rule. WU Br. at 40-43 (8th Cir. filed Aug. 25, 2006).

Even less plausible is the University's argument that the meaning of the Common Rule is not dispositive in this case. Br. in Opp. at 16-17. Petitioners' argument is that the Common Rule bars research participants from consenting to the surrender of the ownership of their tissue. The lower courts found that Petitioners *had* in fact donated their tissues, a result that is incompatible with Petitioners' interpretation of the regulation. The University seems to suggest that the preemption would only affect some of the language in the informed-consent forms given to Petitioners, arguing that the Eighth Circuit correctly found that other language, combined with various other circumstances, sufficed to establish donative intent. But that misses the point. The Common Rule bars the University from even asking for a transfer of ownership and preempts *any* language in the forms that might effect such a transfer – even if that language does not expressly address the issue of ownership. The Court of Appeals had no plausible basis for ignoring this fundamental problem with its analysis.

2. The University also now tries to defend the outcome below as being "correct." Br. in Opp. at 22. But the University attached a letter it received from OHRP showing precisely the opposite. That letter makes plain – contrary to the University's position – that the regulation's prohibition on "exculpatory" language does not bar only waivers of negligence claims. Instead, OHRP interprets the regulation to bar the waiver of *any* legal right the research

participant has under state law, including ownership of tissue samples.

> [E]xcept in jurisdictions in which it has been conclusively determined that all research subjects have no legal rights in their excised human biological material, *OHRP continues to find language that waives any such legal rights on the part of research subjects to be exculpatory.* We believe that, to date, no jurisdictions have conclusively determined that all human subjects have no legal rights in their excised biological material that is used for research purposes.

Br. in Opp. at 5a (emphasis added).

The Eighth Circuit held that in light of the "language contained in the consent forms and brochures" that spoke of "donation," Pet. App. at 13a, 16a & n.7, Petitioners surrendered their ownership rights in their tissue. But that is precisely what the federal regulation, and OHRP's interpretation of the exculpatory language clause, prohibit. The tissues unquestionably belonged to Petitioners unless they validly consented to waiver of their ownership rights. And under the Common Rule, they could not make such a waiver.[1]

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[1] Thus, whatever OHRP's position might have been several decades ago, *see* Br. in Opp. at 23 (citing 1989 letter), it is plain that under OHRP's current view the federal regulations do, in fact, prohibit outright donation of tissues for research: federal law guarantees a continuing right to withdraw from research,

The University entirely ignores the fact that the OHRP letter supports *Petitioners'* interpretation. Instead, it adverts to dictionary definitions in attempt to bolster its own contrary view. Br. in Opp. at 22. But OHRP's interpretation is controlling under hornbook principles of administrative law, so long as it is not "plainly erroneous," which it is not. *Long Island Care at Home, Ltd. v. Coke*, 127 S. Ct. 2339, 2349 (2007).

The University's invocation of the *Moore* and *Greenberg* cases, Br. in Opp. at 18-20, is particularly inapposite. Neither of those cases involved an interpretation of the Common Rule because neither involved donation of tissue for federally funded research covered by the Common Rule. Nor did either case involve interpretation of a written informed-consent document. Indeed, *Moore* specifically held that research participants could look to the protections of written informed consent, the very protections that the Common Rule enforces. *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 494 (Cal. 1990).

Perhaps tacitly recognizing that the OHRP letter supports Petitioners on the critical question whether the Common Rule permitted the University even to ask for tissue donations (as opposed to the right to *use* tissues subject to the RPs' right to withdraw consent later), the University argues in the alternative that the regulation is not enforceable. The University begins with the red herring that the

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and the informed consent document cannot contain any language suggesting that the patient waived a right.

Common Rule does not create a private right of action. Br. in Opp. at 21. Yet as Petitioners have explained, they did not bring an action under the Common Rule; rather, they are seeking the protection of the Rule against the University's claim of ownership, brought by the University in a declaratory judgment action. Pet. at 9 n.2. Likewise, OHRP's letter does not bar Petitioners from invoking the Rule. The letter states that it "agrees with the district court that its guidance document on exculpatory language does not have a legally binding effect upon entities regulated by OHRP." Br. in Opp. at 4a. But Petitioners are not seeking to enforce the guidance document; they are seeking to enforce the regulation. Moreover, the district court did not hold that the guidance document "does not have a legally binding effect." It held that the guidance document was legally binding as to waivers of negligence claims. Pet. App. at 47a. In light of what is, at a minimum, the ambiguity of OHRP's interpretation on this point, this Court should at least call for the views of the Solicitor General as to the proper interpretation of the regulation.

3. Finally, contrary to the University's protestations, and consistent with the enormous public interest in this case, Pet. at 13 n.3, the issue presented here is one of great importance. The University downplays the negative consequences of the lower courts' ownership ruling, claiming that the University can be trusted not to abuse its ownership rights or that other legal provisions prevent misuse. But these arguments are unavailing.

First, the University invokes the Common Rule itself as a limitation on its ability to use the samples for controversial research that lies beyond the scope of the original protocol approved by the patient. Br. in Opp. at 28. Yet it has been the University's position throughout the litigation that once it deidentifies the tissue samples, they are no longer protected by the Common Rule. Pet. at 15, 18-19. Indeed, the Brief in Opposition contains a lengthy footnote reserving the University's right to deidentify the samples. Br. in Opp. at 30 n.11. By the University's own account, the Common Rule is no bar to misuse of the tissues.

Second, the University protests that it can be trusted not to cash in on its ownership rights. Leaving aside the evidence in the record that suggests otherwise, Pet. at 14, the Eighth Circuit's ruling covers far more institutions than just the University. In the face of the Eighth Circuit's bestowal of property rights, under state law and notwithstanding the federal regulation, other institutions may use samples for monetary gain. And, in a world where information contained in fresh frozen tumor samples does (and in the future increasingly will) affect treatment choices, selling off samples will harm the research participants and their families.

Third, and relatedly, the Eighth Circuit's decision will dramatically change the way research samples are used and will have a profound effect on the willingness of individuals to participate in research in the first place. The Common Rule exists to safeguard informed consent in the sensitive and

morally complicated area of human subject research. Under the Eighth Circuit's rule, individuals – people just like Petitioners – can be held to have waived all say in the future use of their tissues, despite the Common Rule's express regulation to the contrary. That decision is worthy of this Court's review in order to ensure that the protections provided by federal law are more than paper rights.

CONCLUSION

For all of these reasons, as well as those set forth in the opening petition, Petitioners ask that the Court grant review in this case.

Respectfully submitted,

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